

## REMARKS

In the Final Office Action dated July 23, 2008, the Examiner rejected claims 12 and 14-20. In reply, Applicants submitted an Amendment and Response on November 21, 2008. In an Advisory Action dated December 24, 2008, the Examiner refused to enter the amendments submitted on November 21, 2008. Accordingly, claims 12 and 14-20 as set forth in the response dated April 4, 2008 are pending.

In this Request for Continued Examination, Applicants have amended claims 12, 16, and 17; cancelled claims 15 and 19; and added new claims 21-37. Support for the amendments and new claims can be found generally throughout the specification and claims as originally filed; *see, e.g.*, paragraphs [0005]-[0007], [0010], [0012], [0016], [0023], [0038], [0043], [0059], [0061], [0075], [0078], [0083]-[0085], and [0115]. No new matter has been added. Accordingly, after entry of the amendments herein, claims 12, 14, 16-18, and 20-37 will be pending.

In light of the amendments and the remarks herein, Applicants respectfully request reconsideration and allowance of the pending claims.

### Supplemental Information Disclosure Statement

Applicants submit herewith an Information Disclosure Statement and request the Examiner to carefully consider and initial the same.

### Withdrawal of Hydrate Species

The Examiner alleged that Applicant's amendment to add a hydrate species to the claims was drawn to a non-elected species. Without acquiescing in the Examiner's allegation, and solely to further prosecution, Applicants have deleted all reference to a hydrate species from the pending claims. Applicant reserves the right to pursue hydrate species without prejudice in one or more continuation applications.

### Rejection under 35 U.S.C. § 102(b)

The Examiner rejected claims 12 and 14 under 35 U.S.C. § 102(b) as being unpatentable over Funahasi *et al.*, WO 02/032872 (hereinafter "Funahasi"). In particular, the Examiner

asserted that Funahashi disclosed the elected compound and its utility for inhibition of tumor and cancer cell proliferation, for anti-angiogenesis, and as a pulmonary treatment agent. The Examiner concluded, with respect to the elected species of small cell lung cancer, that given Funahashi's teachings regarding the treatment of cancer and angiogenesis, one of ordinary skill in the art would have had a reasonable expectation of success that the elected compound could in fact be an effective treatment for small cell lung cancer.

Applicant respectfully disagrees with the rejection, particularly with respect to the claims as currently amended. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference. *See Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). As amended, independent claim 12 recites a step of determining if a patient's cancer expresses c-Kit kinase or a mutant c-Kit kinase. Funahashi does not disclose such a step of determining if a patient's cancer expresses c-Kit kinase or a mutant c-Kit kinase. In fact, Funahashi is completely silent as to determining the expression of c-Kit kinase or a mutant c-Kit kinase in any cancer, let alone the elected small cell lung cancer.

Because the Funahashi reference clearly does not teach the recited limitation, it cannot anticipate claims 12 or 14. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejected claims 12 and 14-20 under 35 U.S.C. § 103(a) as being unpatentable over Funahashi in view of Hibi *et al.* ("Hibi"). In particular, the Examiner reiterated his comments under the § 102(b) rejection regarding the teachings of Funahashi, and further noted that Hibi discloses that c-Kit is expressed in small cell lung cancer. The Examiner concluded that one of ordinary skill in the art would have been motivated to use the elected compound in the claimed methods since Funahashi teaches it as an effective pulmonary agent and Hibi teaches c-Kit expression in the elected small cell lung cancer. Moreover, the Examiner acknowledged that Funahashi did not explicitly disclose the c-Kit inhibiting properties of the elected compound, but alleged that the c-Kit inhibiting properties of the elected compound were inherent properties.

Applicant respectfully disagrees with the rejection, particularly with respect to the claims as currently amended. Independent claims 12 and 17, as amended, recite steps of determining if

a patient's cancer or a cell, respectively, expresses c-Kit kinase or a mutant c-Kit kinase. As acknowledged by the Examiner, Funahashi is silent as to the inhibitory activity of the elected compound on c-Kit kinase. Moreover, Funahashi also does not disclose the expression of c-Kit in any cancer, let alone the elected small cell lung cancer, nor does Funahashi disclose or suggest that one should determine if a patient's cancer or a particular cell of interest expresses c-Kit kinase or a mutant c-Kit kinase before administration of one of the Funahashi compounds. One of ordinary skill in the art would thus find no reason or motivation to modify the cancer treatment methods in Funahashi to perform an additional step of determining c-Kit or mutant c-Kit expression prior to administration of a Funahashi compound for treating a cancer. The Examiner has provided no logical rationale why one having ordinary skill in the art would so modify the treatment methods of Funahashi to include the recited determining step given Funahashi's silence as to the c-Kit inhibiting property of the recited molecule.

Hibi fails to cure the deficiencies of Funahashi. Merely because Hibi teaches that c-Kit is expressed in small-cell lung cancer provides no logical reason for one having ordinary skill in the art to modify the methods of Funahashi to add an additional step to determine if a patient's cancer or a cell expresses c-Kit before administration of the recited compound, particularly given the fact that both Funahashi and Hibi are silent as to the c-Kit inhibiting properties of the recited compound. The Examiner has provided no rationale why the mere fact that small cell lung cancer expresses c-Kit would prompt one having ordinary skill in the art to insert a step of determining if a patient's cancer or a cell expresses c-Kit prior to administering a Funahashi compound for treating cancer, when both Funahashi and Hibi are silent as to the c-Kit inhibiting properties of the elected compound. Funahashi's and Hibi's total lack of disclosure and appreciation of such an alleged inherent property precludes a finding that one having ordinary skill in the art would be motivated by their teachings to modify Funahashi to include a step of determining c-Kit or mutant c-Kit expression. Applicants note that the Federal Circuit has held that the inherency of an advantage and its obviousness are entirely different questions (*In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990)). “[A] retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in the particular claimed combination” (*In re Newell*, 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989)). Accordingly, Applicants respectfully assert that the Examiner

Applicant : Yamamoto et al.  
Serial No. : 10/797,903  
Filed : March 10, 2004  
Page : 11 of 12

Attorney's Docket No.: 25142-0002001 / FP04-0096-  
00US-XX

has not made out a *prima facie* case of obviousness, and request withdrawal of the rejections of independent claims 12 and 17, and claims dependent thereon.

With respect to independent claim 16, the Examiner has not pointed to anything in Funahasi or Hibi, or indeed any other reference, that teaches or suggests use of the elected compound for treating mastocytosis, allergy, or asthma. Accordingly, Applicants respectfully assert that the rejection is improper.

Given all of the above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Applicant : Yamamoto et al.  
Serial No. : 10/797,903  
Filed : March 10, 2004  
Page : 12 of 12

Attorney's Docket No.: 25142-0002001 / FP04-0096-  
00US-XX

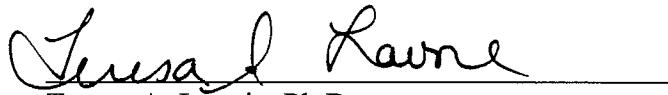
## CONCLUSION

Applicants respectfully assert that the claims are in condition for allowance, which action is hereby requested. The Examiner is invited to telephone the undersigned attorney if such would expedite prosecution.

Please charge deposit account 06-1050 for the excess claim fees (6 additional claims) and for the Petition for Extension of Time fee (3 month extension). Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: 6/23/09



Teresa A. Lavoie, Ph.D.  
Reg. No. 42,782

Fish & Richardson P.C.  
3200 RBC Plaza  
60 South Sixth Street  
Minneapolis, Minnesota 55402  
Telephone: (612) 335-5070  
Facsimile: (612) 288-9696